K112933

DEC 27 2011

BECKMAN COULTER

510(k) Summary
Prepared December 14, 2011

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

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Device Name

Trade Name:	Access Thyroglobulin Antibody II for use on the Access Immunoassay Systems
Common Name:	Thyroglobulin Antibody Enzyme Immunoassay
Classification Name:	Immunochemical, Thyroglobulin Autoantibody

Predicate Device

Access Thyroglobulin Antibody II (k062516)
Manufactured by Beckman Coulter, Inc.

Device Description

The Access Thyroglobulin Antibody II reagents, Thyroglobulin Antibody II calibrators, and the Access Immunoassay analyzers comprise the Access Immunoassay System for the quantitative determination of thyroglobulin antibody in human serum and plasma.

Intended Use

The Access Thyroglobulin Antibody II (TgAb II) assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thryoglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of Hashimoto's disease, nontoxic goiter, and Graves' disease.

Comparison of Technological Characteristics

Parameter	Access TgAb II (k112933)	Predicate Access TgAb II (k062516)
Intended use	The Access Thyroglobulin Antibody II assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of Hashimoto's disease, nontoxic goiter, and Graves' disease.	The Access Thyroglobulin Antibody II assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of Hashimoto's disease, nontoxic goiter, and Graves' disease.
Analyte Measured	Thyroglobulin Antibody	Thyroglobulin Antibody
Standardization	NIBSC Anti-Thyroglobulin Serum, Human First International Reference Preparation, WHO Coded 65/93	NIBSC Anti-Thyroglobulin Serum, Human First International Reference Preparation, WHO Coded 65/93
Technology	Sandwich immunoassay	Sandwich immunoassay
Format	Chemiluminescent	Chemiluminescent
Method	Automated	Automated
Calibration	Utilizes a stored calibration curve	Utilizes a stored calibration curve
Sample Type	Serum or plasma	Serum or plasma
Measuring Range	0.9 – 2500 IU/mL	0.9 – 2500 IU/mL

Summary of Studies

Method Comparison: A comparison of thyroglobulin antibody values from 397 samples, ranging from approximately <0.9 to 2500 IU/mL, was run with both the Access Thyroglobulin Antibody II immunoassay and the predicate Access Thyroglobulin Antibody II immunoassay. The new method (y-axis) was correrlated with the predicate (x-axis) using Passing-Bablock analysis, the following relationship was observed: new = m(predicate)1.0 ± 0.12, $R^2 \geq 0.92$.

Imprecision: Within run imprecision ranged from 3.6 to 5.7 %CV, between run imprecision ranged from 0.0 to 5.2 %CV, and total imprecision ranged from 4.8 to 7.7 %CV at levels between 26.9 and 1889.6 IU/mL. The assay exhibits total imprecision of less than 10% CV for concentrations greater than or equal to 15 IU/mL and < 1.5 IU/mL SD at concentrations < 15 IU/mL.

High-dose Hook Effect: The Access Thyroglobulin Antibody II assay demonstrated no hook to 50,000 IU/mL.

Linearity: The Thyroglobulin Antibody II assay has demonstrated to be linear across the range of the assay (0.0 to 2500IU/mL).

Limit of Blank (LoB): The highest measurement result observed with no analyte present in a sample is 0.9 IU/mL (n=221).

Limit of Detection (LoD): The lowest concentration of analyte in a sample that can be detected with a stated probability (95%) is 0.9 IU/mL.

Analytical Specificity: There is no significant interference from total protein, bilirubin, hemoglobin, or trigycerides. Additionally, samples with autoimmune disease state were tested and showed 100% total agreement.

Conclusion:

The Access Thyroglobulin Antibody II assay, for use on the Access Immunoassay Systems, is substantially equivalent to the predicate device, Access Thyroglobulin Antibody II assay (k062516) for the measurement of thyroglobulin antibody.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Beckman Coulter, Inc.
Immunodiagnostic Development Center
c/o Ms. Geraldine L. Baglien
Senior Regulatory Affairs Specialist
1000 Lake Hazeltine Dr.
Chaska, MN 55318-1084

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Re: k112933
Trade/Device Name: Access Thyroglobulin Antibody II Assay
Regulation Number: 21 CFR §866.5870
Regulation Name: Thyroid Autoantibody immunological test system
Regulatory Class: Class II
Product Code: JNL, JIT
Dated: December 14, 2011
Received: December 15, 2011

Dear Ms. Baglien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K112933

Device Name: Access Thyroglobulin Antibody II Assay on the Access® Immunoassay Systems

Indications For Use:

The Access Thyroglobulin Antibody II assay is a paramagnetic chemiluminescent immunoassay for the quantitative determination of thyroglobulin antibody levels in human serum and plasma using the Access Immunoassay Systems. The measurement of thyroid autoantibodies may aid in the diagnosis of Hashimoto's disease, nontoxic goiter, and Graves' disease.

Prescription Use ___X___ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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